charge deposit account No. **13-2546**, in the name of Medtronic, Inc., the fee under 37 C.F.R. §1.17(c) for a four-month extension of time (or for any necessary fees related to their response).

In response to the Office Action dated September 27, 2000, Paper No. 3, please amend this application as follows:

I. AMENDMENTS IN THE CLAIMS

1. Cancel, without prejudice, claims 15-19, 43-47, and 51-61 inclusive.

2. Applicants submit herewith:

A. A clean version of the amended claims;

B. A marked-up version of the claims;

The submitted marked-up version of the claims follows standard amendment rules, wherein added text has been underlined and deleted text has been bracketed. Applicants respectfully request entry of the submitted amendments.

II. EXPLANTATION OF THE AMENDMENTS IN THE CLAIMS

First, applicants have cancelled claims 15-19, 43-47, and 51-61 in view of the submitted amendments.

Second, Applicants submit that the amended claims are fully supported by the specification as filed, and does not add new matter.

Applicants have amended claims 1, 6, 9, 10, 14, 20, 22, 23, 24, 39, 40, 41, 42, 48, and 49 to replace the terms "genetic material' or "conduction protein genetic material" occurring after the preambles of the claims. The previous terms are replaced with "recombinant nucleic acid vectors encoding a conduction protein selected from the group Cx40, Cx43, and Cx45." Where antecedent basis for the given conduction proteins previously exists, the replacement terminology reads "said recombinant nucleic acid vectors."

Support for the amendment language can be found at several locations in the specification: e.g, definitions of "conduction protein genetic material" on p. 18, ll. 4-8, and further the definition of "recombinant nucleic acid molecule" on p. 18, l. 13- to p. 19, l.11. Additional support for the amendments is found on, p.6, ll. 9-12, p.7, ll. 1-4, p. 9, ll. 8-12, and elsewhere in the application.

Claim 25 has been amended to replace the term "peelable" introducer sheath to "removable" introducer sheath. This terminology was suggested by the examiner. Support for this change can be found in the specification at p. 16, ll. 2-4

III. RESPONSE TO THE REJECTIONS MADE IN THE SECOND OFFICE ACTION

In the communication from the Examiner mailed February 2, 2001, the Examiner rejected claims on the following bases:

(1) Claims 1, 4-25, 39-54, and 61 were newly rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention;

(2) Claims 1, 4-15, 17-18, 20-25, 39-43, 45-46, 48-51, 53-54, and 61 were newly rejected under 35 U.S.C. Section 112, first paragraph, for lack of written description.

(3) Claims 25 stands rejected under 35 U.S.C. Section 112, second paragraph.

(4) Claims 1, 4-25, and 39-55 stand rejected under 35 U.S.C. 103, as being unpatentable over Mulier et al. (WO 95/05781) in view of Leiden et al. (WO 94/11506) and Kanter et al. (1994).

Response to each of the foregoing rejections are provided below, where each response references the number corresponding to each rejection set forth above.

IV. Responses to Rejections Made in the First Office Action

(1) Applicant assert they have overcome Rejection of 112, first paragraph, in view of obviousness arguments by the examiner and by the provided amendments.

Claims 1, 4-25, 39-54, and 61 were newly rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In connection with the present rejection under 112, first paragraph, the examiner has also argued in the present communication and in the previous arguments that it would be obvious to one skilled in the art to make and use the invention based on the teachings of Mulier et al. in view of Leiden et al. and Kanter et al. under 35 U.S.C. §103. These two views are incongruent. It is difficult to reconcile the examiner's argument that the application does not enable one skilled in the art to make the invention, while later on arguing that one skilled in the art knows how to make and use the claimed invention. Accordingly, Applicants respectfully request the Examiner to remove the rejection under 35 U.S.C. §112, first paragraph, having previously placed into issue whether the claims are obvious under 35 U.S.C. § 103 (addressed in part (4) of this section).

Second, in view of moving forward prosecution, applicants have amended Claims 1, 6, 9, 10, 14, 20, 22-24, 39, and 40 so that all the

pending claims are specifically directed to the connexin family members Cx40, Cx42, and Cx45 provided in a nucleic acid vector. Applicants believe that having focused the claims to the particular members of the connexin family delivered in a nucleic acid vector that the application is fully enabled to the scope of the amended claims and respectfully, request reconsideration and removal of the present rejection under 35 U.S.C. §112, first paragraph.

(2) Claims 1, 4-15, 17-18, 20-25, 39-43, 45-46, 48-51, 53-54, and 61 have been amended to overcome the rejection under 35 U.S.C. Section 112, first paragraph, for lack of written description.

Claims 1, 4-15, 17-18, 20-25, 39-43, 45-46, 48-51, 53-54, and 61 were newly rejected under 35 U.S.C. Section 112, first paragraph, for lack of written description. Specifically, the examiner indicated that the specification did not provide adequate written description for genetic material encoding a conduction protein capable of affecting cardiac conduction other than nucleic acid vectors encoding a connexin family member other than Cx40, Cx 43, and Cx45 and their incorporation in a vector.

Applicants have amended Claims 1, 4-15, 17-18, 20-25, 39-43, 45-46, 48-51, 53-54, and 61 so that the claims are specifically directed to the connexin family members Cx40, Cx42, and Cx45 provided in a nucleic acid vector. Applicants respectfully submit, in view of the submitted amendments, that the present rejection under 112, first paragraph, has been overcome and request removal of the standing rejection.

(3) Amendments to Claim 25 overcome the rejections made under 35 U.S.C. Section 112, second paragraph.

Rejection of Claim 25 was maintained after considering Applicant's previous arguments under 35 U.S.C.§ 112, second paragraph.

The examiner has kindly suggested that the claims be amended to recite a "removable introducer sheath." Applicants submit amended Claim 25 incorporating the suggested language of the examiner. Applicants again wish to thank the examiner for the suggested language and request removal of the standing rejection.

(4) Claims 1, 4-25 and 39-55 are not obvious over Mulier et al. (WO 95/05781) in view of Leiden et al. (WO 94/11506) and Kanter et al. (1994) because Mulier et al. teaches away from the intended function of delivering genetic material to cardiac tissue and thereby is not a properly combinable reference.

The present invention is directed to restoring or correcting conduction disturbances in cardiac tissues with Cx40, Cx43, and Cx45. One skilled in the art reading Mulier would not use the Mulier device for introducing genetic material for restoring cellular tissue. The Mulier device is described as an ablation catheter, wherein the essential goal is to destroy cardiac tissues, *i.e*, to produce lesions. One would not use such a device to restore cardiac tissue and thereby one would not combine this device with the teaching of Leiden or Kanter to restore conductive cell function. Further, this is supported by the described function of the Mulier reservoir. Mulier uses the reservoir to deliver Ringer's solution to improve conductivity in the area to be destroyed. Nowhere does Mulier suggest the reservoir is part of the delivery of genetic materials for the purpose of providing new conductive proteins to establish new cellular tissue. In fact, Mulier in essence teaches a device for destroying cellular conductivity and thereby teaches away from a device used to promote conductivity by

providing new cellular tissue. As such, Mulier is not a properly combinable reference because the intended function of the Mulier device is to destroy tissue, and thereby there would be no technological motivation for combining Mulier with the other cited references. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Applicants respectfully request reconsideration and removal of the present rejection.

Respectfully submitted,

8/31/01

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